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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,105	09/12/2003	Hans S. Keirstead	IRVN-009CON	6563
24353	7590	06/29/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			KOLKER, DANIEL E	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,105

Applicant(s)

KEIRSTEAD ET AL.

Examiner

Daniel Kolker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/12/03, 3/4/04, 3/11/04, 3/23/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The preliminary amendment filed 12 September 2003 has been entered. Claims 1 – 34 are canceled; claims 35 – 58 are new. Claims 35 – 58 are pending and under examination.

Information Disclosure Statement

2. The information disclosure statements have been considered. It is not immediately apparent how US Patent 5,830,621 (Suzuki et al. cited on the IDS filed 12 September 2003) is relevant. The '621 patent is on point to photosensitive elastomers and rubber plates, which seem to be unrelated to the claimed invention. The reference by Bain et al. on the IDS filed has no journal name or date and thus the examiner cannot determine if it constitutes prior art. The reference has not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 – 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 35 and 47 both recite the phrase “a differentiated cell population as part of a system” in the preamble, and also recite “wherein the system further comprises” at the end of the claim. It is not clear whether applicant is attempting to claim as his invention a differentiated cell population, or “a system” comprising the cell population and the line of pPS cells from which they were produced. It is unclear whether the “system” is a required element of the claimed invention, or whether it is an intended use of the cell population. Thus a skilled artisan could not determine the metes and bounds of the claim, and could not determine whether the differentiated cell population in the absence of the remainder of the system would read on the claimed invention. The remaining claims (36 – 46 and 48 – 58) are rejected because they depend from a rejected base claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35 – 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Washington University (WO 01/28342, cited on IDS filed 12 September 2003) as evidenced by Wilson (2003. *Glia* 44:153 – 165).

WO 01/28342 (hereinafter, the '342 reference) teaches methods of isolating oligodendrocyte-enriched cultures. The '342 reference specifically teaches that ES cells (embryonic stem cells) are to be used as a starting material, and that primate cells, and in particular human cells, are the preferred types (see p. 6 line 25 – p. 7 line 8). The specification (p. 8 paragraph [0063]) defines primate pluripotent stem cells to include embryonic stem cells, which is relevant to the first bulleted point of claim 35. Beginning on p. 18, the '342 reference teaches the artisan how to grow cultures enriched in oligodendrocytes starting from ES cells. While the example uses rodent tissue, the reference explicitly states that tissue from other species including humans and monkeys will work just as well (p. 8 lines 3 – 9). The example on pp. 18 – 19 teaches production of cultures that are $92 \pm 7\%$ oligodendrocytes (see p. 19 lines 8 - 14), which exceeds the "at least ~80%" limitation in claim 35. The reference also teaches that these are both mature and immature oligodendrocytes, and that they come from "oligospheres". The '342 reference also teaches that the oligospheres are NeuN-negative (see Table 1 on p. 18), and since oligodendrocytes do not express NeuN, they must be NeuN-negative as well. The specification (p. 8, paragraph [0058]) discloses that oligodendrocyte precursors are those cells which can form oligodendrocytes and/or precursor cells. Since the '342 reference teaches that both oligodendrocytes and pure cultures of oligospheres which contain no astrocytes, it teaches "oligodendrocyte precursors" as defined in the specification. Thus the '342 reference teaches the differentiated cell population recited in claim 35.

The examiner concedes that the '342 reference does not explicitly teach that the oligodendrocytes stain with antibody specific for NG2 proteoglycan, which is recited in claim 35, or whether they express AB25, recited in claim 36, or whether they express PDGFR α , recited in claim 37. However Wilson teaches that these three markers are all characteristic of oligodendrocyte precursor cells (see abstract and p. 154, first column, for example) and that they are in fact expressed on human oligodendrocyte precursors (see p. 157 – 159). Thus the culture from the '342 reference has cells which inherently have the markers recited in claims 35

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– 37. Claim 38 is rejected because the reference teaches the cells which become oligodendrocytes, thus they must have those features which are characteristic of themselves.

Claims 39 and 40 are drawn to certain functional properties of the claimed culture. The '342 reference is silent as to what will happen when those cells are cultured on poly-L-lysine and laminin in the absence of mitogens. However, since a product and all its properties are inseparable, and the '342 reference teaches the products of claim 35, the claimed products necessarily have the properties recited in claims 39 and 40. Claim 41 is rejected because the '342 reference explicitly teaches implanting the oligospheres into *shiverer* mutant mice and teaches that doing so results in remyelination of host axons (see p. 19 line 31 – p. 20 line 23). Claim 42 is rejected because the reference teaches that the cells in fact cause improvement of locomotion (see paragraph spanning pp. 20 – 21).

Claims 43 – 45 are product-by-process claims. Since the prior art reference teaches the claimed product, how it is made does not affect patentability. See MPEP § 2113. Claim 46 is rejected because the prior art reference teaches the use of human embryonic stem cells

Claim 47 is rejected for the same reasons claim 35 is rejected. The examiner concedes that the reference does not teach whether or not the cells are positive for transcription factor Olig1. However this is an inherent property of the claimed product. As a product and all its properties are inseparable, and the prior art reference teaches the product as set forth above, claim 47 is anticipated as well. Applicant is reminded that once a case of inherency has been set forth, the burden shifts to applicant to distinguish the claimed invention from the prior art. See MPEP § 2112(I) and § 2112(V). Note that in this case the prior art reference teaches several markers expressed on the cells, and the post-filing reference by Wilson teaches that human oligodendrocyte precursors have many of the other markers recited in the claims.

Claims 48 – 58 are similar to claims 36 – 46 and differ only in that they depend from claim 47 rather than claim 35. Thus the reasons that claims 36 – 46 are rejected also apply to claims 48 – 58. For the sake of brevity, applicant is referred to the preceding paragraphs for a detailed description of how the prior art '342 reference anticipates every claim limitation.

Conclusion

5. No claim is allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

June 15, 2006



ROBERT C. HAYES, PH.D.
PRIMARY EXAMINER